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of

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/440,462	11/15/1999	WALID NAJIB ABOUL-HOSN	032301-047	2975
7590	12/04/2003		EXAMINER	
Daniel D Ryan Ryan Kromholz & Manion S C P O Box 26618 Milwaukee, WI 53226			BLANCO, JAVIER G	
			ART UNIT	PAPER NUMBER
			3738	18
DATE MAILED: 12/04/2003				

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>
	09/440,462	ABOUL-HOSN ET AL.
	<b>Examiner</b>	<b>Art Unit</b>
	Javier G. Blanco	3738

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 28 August 2003.
- 2a) This action is FINAL.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-5,7-18 and 47 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 1-5,7-18 and 47 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. §§ 119 and 120

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) All b) Some \* c) None of:  
1. Certified copies of the priority documents have been received.  
2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 13) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.  
a) The translation of the foreign-language-provisional-application has been received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

#### Attachment(s)

- |   |  |
|---|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                   | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ . |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                          | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)  |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>17</u> . | 6) <input type="checkbox"/> Other: _____                                     |

**DETAILED ACTION**

***Continued Examination Under 37 CFR 1.114***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on August 28, 2003 has been entered as Paper # 16.

***Response to Amendment***

2. Applicant's cancellation of claims 6, 19-46, 48, and 49 in Paper No. 17 is acknowledged.

***Priority***

3. It is noted that this application claims the benefit of Applications Serial Number 09/079,836 and 09/231,320 (see Paper # 14, filed January 29, 2003). The current status of these applications should be included (i.e., 09/079,836, now US 6,395,026).

4. Acknowledgment is made of applicant's claim for foreign priority based on International Application No. PCT/US99/10871 filed in USA on May 17, 1999. It is noted, however, that applicant has not filed a certified copy of the International Application as required by 35 U.S.C. 119(b).

***Drawings***

5. This application has been filed with informal drawings, which are acceptable for examination purposes only. Formal drawings will be required when the application is allowed.

***Claim Rejections - 35 USC § 112***

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 1-5, 7-18, and 47 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention:

- a. Regarding claims 1 and 47, the new claim limitation “the inner and outer cannulas forming between them a lumen defining a second flow path” (see claim 1, line 6; claim 47, lines 6-7) was not disclosed/described in the specification. According to the specification (see page 28) and the Figures (see for example Figure 1), concentric cannula 120 comprises outer conduit 123 (outer cannula) and inner conduit 121 (inner cannula). There is an annular space or lumen formed between outer conduit 123 and inner conduit 121. That annular space or lumen provides for the inflow of blood to pump 124 (a “first flow path” or intake of blood). As seen in Figure 1, the arrows show blood flowing into the annular space or lumen formed between outer conduit 123

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and inner conduit 121. The "second flow path" or output of blood is shown in Figure 1 by arrows flowing inside inner conduit 121.

b. Applicants have failed to specifically point out the support in the original disclosure for each of the newly presented claim limitations (see M.P.E.P. 714.02).

Because of the procedure outlined in M.P.E.P. 2163.06 for interpreting the claims, it is noted that other art may be applicable under 35 U.S.C. 102 or 35 U.S.C. 103(a) once the aforementioned problem is corrected.

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. Claims 1-5, 7-18, and 47 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

a. Regarding claim 1, "the first and second flow paths" (see line 9) or "first flow path" (see line 10) lacks antecedent basis.

b. Regarding claim 8, it depends on cancelled claim 6.

c. Regarding claim 47, "the first and second flow paths" (see line 9) or "first flow path" (see line 10) lacks antecedent basis.

### *Conclusion*

10. The prior art made-of record-and-not-relied-upon-is-considered-pertinent-to-applicant's

disclosure: Aboul-Hosn et al. (US 6,532,964 B2).

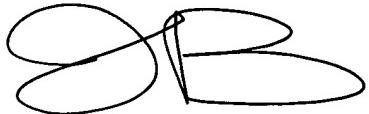
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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Javier G. Blanco whose telephone number is 703-605-4259. The examiner can normally be reached on M-F (7:30 a.m.-4:00 p.m.), first Friday of the bi-week off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on 703-308-2111. The fax phone numbers for the organization where this application or proceeding is assigned is 703-872-9306 for regular communications and After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.

JGB



November 28, 2003



David H. Willse  
Primary Examiner